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T. Laine
T. Lund
M. Ylikoski
J. Lohikoski
D. Schlenzka

Accuracy of pedicle screw insertion with and without computer assistance: a randomised controlled clinical study in 100 consecutive patients

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T. Laine (✉) · T. Lund · M. Ylikoski
J. Lohikoski · D. Schlenzka
ORTON Orthopaedic Hospital,
Invalid Foundation, Helsinki, Finland
e-mail: timo.laine@invalidisaatio.fi,
Tel.: +358-9-47481,
Fax: +358-9-4748 2334)

T. Laine
Tenholantie 10, 00280 Helsinki, Finland

Abstract We performed a randomised controlled study to assess the accuracy of computer-assisted pedicle screw insertion versus conventional screw placement under clinical conditions. One hundred patients scheduled for posterior thoracolumbar or lumbosacral pedicle screw instrumentation were randomised into two groups, either for conventional pedicle screw placement or computer-assisted screw application using an optoelectronic navigation system. From the computer-assisted group, nine patients were excluded: one because of an inadequate preoperative computed tomography study, seven because of problems with the specific instruments or the computer system, and one because of an intraoperative anesthesiological complication. Thus, there were 50 patients in the conventional group and 41 in the computer-assisted group, and the number of screws inserted was 277 and 219, respectively. There was no statistical difference between the groups concerning age, gender, diagnosis, type of operation performed, mean operating time, blood loss, or number of screws inserted. The time taken for screw insertion was significantly longer in the computer-assisted group. Postoperatively, screw positions were assessed by an independent radiologist using a sophisticated CT imaging protocol. The pedicle perforation rate was 13.4% in the conventional group and 4.6% in the computer-assisted group (P = 0.006). Pedicle perforations of more than 4 mm were found in 1.4% (4/277) of the screw insertions in the conventional group, and none in the computer-assisted group. Complications not related to pedicle screws were two L5 nerve root lesions, one end plate fracture, one major intraoperative bleeding and one postoperative death in the conventional group, and one deep infection in the computer-assisted group. In conclusion, pedicular screws were inserted more accurately with image-guided computer navigation than with conventional methods.

Key words Spine surgery · Computer-assisted surgery · Pedicle screws · Image guidance · Randomised controlled trial

Introduction

Transpedicular screws are commonly used for intervertebral fixation in various spinal disorders. Pedicle perforation rates of between 21.1 and 39.8% have been reported in clinical studies with adequate postoperative computed tomography (CT) control when conventional methods, based on anatomical landmarks and intraoperative fluoroscopy, have been used for screw insertion [2–4, 6]. A higher accuracy, with perforation rates of between 4.3 and 14.3% has been achieved using computer-assisted techniques [1, 5, 7, 8, 12]. No randomised controlled clinical trials comparing conventional versus computer-assisted pedicle screw insertion are available to date.

An optoelectronic navigation system, developed at the Maurice E. Müller Institute for Biomechanics, Bern, Switzerland, has been in clinical use at our hospital since 1995 [9–12]. The first clinical experiences, based on a prospective series of 30 patients, have been reported earlier [7]. The current updated software with surface matching and a three-dimensional computed tomography model (SurgiGATE Spine 2.1, Medivision, Oberdorf, Switzerland) has been used since April 1998.

The purpose of the present study was to evaluate whether pedicle screws can be inserted more accurately and safely with computer assistance than with conventional methods in a randomised controlled series of 100 consecutive patients.

The authors did not have any commercial affiliations to the manufacturers of the navigation system used in this trial.

Materials and methods

One hundred consecutive thoracolumbar and lumbosacral fusions were performed by the authors (T.L. and T.L.) between April 1998 and June 1999. The patients, 60 women and 40 men, were randomly allocated, using sealed envelopes, into two groups for either conventional or computer-assisted pedicle screw insertion. In the computer-assisted group, nine patients had to be excluded for reasons discussed below. Thus, there were two groups: group 1 (n = 50) with conventional pedicle screw insertion and group 2 (n = 41) with computer-assisted screw insertion. The mean age of the patients was 53 ± 14 (range 22–77) years in group 1, and 54 ± 16 (range 22–82) years in group 2. The indications and types of operation performed are shown in Tables 1 and 2. There was no statistical difference between the groups concerning age, gender, diagnosis, type of operation or instrumentation used.

Preoperatively, spiral CT scans were obtained from all patients randomised for computer-assisted screw insertion. During the preoperative planning, the anatomy of the levels to be instrumented was studied using the planning module of the computer system, which displays the CT scan of the area of interest in four views: axial, sagittal and frontal cuts, as well as a three-dimensional representation. Anatomic landmarks for paired-point matching were registered, and optimal screw trajectories planned. The time used for preoperative planning was registered.

Table 1 Number of operations performed for different indications in group 1 (pedicle screw insertion with conventional techniques) and group 2 (screw insertion with computer assistance)

	Group 1	Group 2	Total
Spinal stenosis	18	15	33
Post-discectomy syndrome	9	4	13
Spondylolysis/olisthesis	8	9	17
Disc degeneration	4	5	9
Deformity	6	4	10
Others	5	4	9
Total	50	41	91

Table 2 Number of different types of operations performed (*PLF* posterolateral fusion, *PLIF* posterior lumbar interbody fusion)

	Group 1	Group 2	Total
PLF	10	10	20
PLF + decompression	24	19	43
Wedge osteotomy	6	1	7
Ligamentoplasty (Graf)	1	0	1
Circumferential fusion	7	7	14
PLIF	2	4	6
Total	50	41	91

Intraoperatively, in both groups, the bony cortex at the screw insertion site was perforated with a sharp awl, and the screw channel was prepared with a blunt pedicle probe. Lumbar 6.7-mm and sacral 8.0-mm Diapason screws were used most commonly; however, in deformities in particular, we preferred to insert lumbar 6.0-mm and sacral 7.0-mm USS pedicle screws. The pedicle screws were inserted according to anatomic landmarks in group 1. The screw position was checked with an image intensifier. In group 2, computer-assisted navigation was used for screw insertion. The details of this procedure have been described earlier [7, 11]. In all patients, the duration of the screw insertion, i.e., the time from finishing the exposure of the spine until all screws had been inserted, was measured. In group 2, this included an instrument calibration check, fixation of the dynamic reference base to the vertebra, matching, accuracy verification, preparation of the screw tracks, and insertion of the screws. Titanium screws were used throughout the series to minimise imaging artefacts. Decompressions were performed after pedicle screw instrumentation. The operating time, blood loss, and intraoperative complications were registered.

Postoperatively, the screw position in the pedicle was verified using a sophisticated computed tomography protocol with transaxial images of the instrumented vertebrae and serial cuts through each pedicle perpendicular to its longitudinal axis as described earlier [6]. The images were assessed by an independent radiologist (M.Y.), who was not aware of the technique of screw insertion. Screw position was staged as: screw inside the pedicle, or perforation of the pedicle cortex by up to 2 mm, from 2 to 4 mm, from 4 to 6 mm, or by more than 6 mm. The location of perforation was classified as lateral, inferior, medial or superior. Neurological as well as other postoperative complications were registered.

In nine patients, classified as dropouts, the operation had to be converted from computer-assisted surgery to conventional techniques. In one case the operation was converted because of an inadequate preoperative CT study, not feasible for use in the computer system. In five patients, a malfunctioning light-emitting diode (LED) of a pedicle probe made navigation impossible. Two operations were converted because of computer hardware errors. One patient developed bronchial obstruction during the procedure, which forced us to abort the operation without planned pedicle screw instrumentation. There was no statistical difference between the two groups and the dropouts concerning age, gender, diagnosis, type of operation or instrumentation used.

The Pearson chi-squared test was used for measuring association between categorical data and the Student's t-test for comparison of means between groups. A P-value of < 0.05 was considered statistically significant.

The study was approved by the ethical committee of the hospital. Informed consent was obtained from all patients.

Results

In groups 1 and 2, a total of 496 titanium pedicle screws (mean 5.5 ± 2.1 screws/patient, range 2–12), were inserted between T8 and S1, of which 380 were Diapason (Stryker, Cestas, France), 112 were USS (Synthes, Waldenburg, Switzerland), and 4 were Graf (SEM, Paris, France) screws. There were 277 (mean 5.5/patient) screws in group 1, and 219 (mean 5.3/patient) in group 2 (NS). The mean time for preoperative planning in the computer-assisted group was 45 ± 24 (range 15–120) min. In 13 patients the preoperative planning revealed important unknown features of the patient's anatomy, such as small, sclerotic or anomalous pedicles, subarticular or far-lateral stenosis and disc herniation, which led to modifications in the operation plan. In group 1, the time taken by preoperative planning was not registered. The mean operating time was 160 ± 73 (range 47–360) min in group 1, and 179 ± 74 (range 95–425) min in group 2 (NS). The mean time used to insert the pedicle screws was 28 ± 17 (range 6–87) min in group 1, and 40 ± 16 (12–76) min in group 2 (P = 0.001). The mean insertion time per screw was 5.1 min in group 1, and 7.5 min in group 2. Four percent (11/277) of the screws had to be repositioned intraoperatively in group 1, but none in group 2. The mean intraoperative blood loss was 1270 ± 1325 (range 100–8000) ml in group 1, and 1107 ± 809 (250–3600) ml in group 2 (NS).

The extent and location of pedicle perforations are shown in Tables 3 and 4. The pedicle perforation rate was 13.4% (37/277) in group 1, and 4.6% (10/219) in group 2 (P = 0.006). The majority of perforations were by less than 4 mm. A pedicle perforation of 4–6 mm was found in 1.4% (4/277) of the screws in group 1, and in none in group 2. No screw was more than 6 mm out of the pedicle. There was a medial or inferior perforation in 10.1% (28/277) of the screws in group 1, and in 0.4% (1/219) of the screws in group 2 (P = 0.00001). There was at least one medial or inferior perforation in 40.0% (20/50) of the patients in group 1, and in 2.4% (1/41) of the patients in group 2 (P = 0.0002).

Table 3 Distribution of pedicle screw positionby extent of perforation and by vertebral level in patients with conventional screw insertion (group 1) and those with computer-assisted pedicle screw insertion (group 2)(0 = screw inside pedicle, 2 = perforation up to 2 mm, 4 = perforation from 2 to 4 mm, 6 = perforation from 4 to 6 mm)

Level	Group 1 (n = 277)				Group 2 (n = 219)				Total
	0	2	4	6	0	2	4	6	
T8	1	1	–	–	–	–	–	–	2
T9	1	1	–	–	2	–	–	–	4
T10	–	–	–	–	3	1	–	–	4
T11	6	–	2	–	4	–	–	–	12
T12	15	3	2		1	–	–	–	21
L1	9	1	–	1	–	–	–	–	11
L2	15	3	1	1	18	–	–	–	38
L3	26	3	–	–	30	2	–	–	61
L4	54	8	1	1	51	2	1	–	118
L5	62	5	1	–	47	3	1	–	119
S1	51	1	–	1	53	–	–	–	106
Total	240	26	7	4	209	8	2	–	496

Table 4 Number of pedicle perforations in different locations

	Group 1	Group 2	Total
Medial	21	1	22
Inferior	7	0	7
Lateral	9	9	18
Superior	0	0	0
Total	37	10	47

There were five major complications in group 1. A partial L5 nerve root lesion developed in a 51-year-old woman and a 50-year-old man. The indication for operation in both was post-discectomy syndrome, the fusion was circumferential (with distraction of disc space), L4–S1 and L5–S1, respectively, the spinal canal was not opened, and on postoperative CT all screws were in the pedicles. One patient had major intraoperative bleeding (4800 + 3200 ml) in a two-stage osteotomy operation. Another patient died 4 weeks after the operation due to pneumonia, sepsis and cardiac arrhythmia. One patient fell down on the 14th postoperative day and suffered an end plate fracture at the upper level (L2) of the instrumentation.

One major complication, deep infection, occurred in group 2. The infection healed after multiple lavations and removal of the instrumentation.

In the eight dropouts with pedicle screws, 49 screws (mean 6.1/patient) were implanted. The mean preoperative planning time was 31 ± 8 (range 20–45) min, mean operating time 168 ± 71 (range 93–285) min, mean pedicle screw insertion time 40 ± 22 (range 23–77) min, and the mean intraoperative blood loss 1081 ± 1007 (range 350–3500) ml. The pedicle perforation rate in the dropouts was 18.4% (9/49 screws). Medial or inferior perforations were found in 6.1% (3/49) of the screws. No complications occurred. There was no statistical difference between the dropouts and group 1. There was a statistical difference between the dropouts and group 2 regarding pedicle perforation rate (P = 0.001) and the number of medial or inferior perforations (P = 0.003).

Discussion

Transpedicular screw insertion is a demanding technique due to considerable variability in the human anatomy and to the fact that it is impossible to guide a screw exactly in three planes of space based on the two-dimensional image information of fluoroscopy. Pedicle screw malplacement rates of between 21.1 and 39.8% have been reported in clinical studies with conventional insertion techniques and an adequate postoperative CT assessment [2–4,6]. Castro et al. [2] reported that 49 out of 123 pedicle screws (39.8%) perforated the pedicle wall. They had five nerve root complications. Gertzbein and Robbins [3] found 48 out of 167 screws (28.7%) penetrating the pedicular cortex. Two of them caused minor neurological complications. In our own previous study with conventional pedicle screw placement [6], 32 out of 152 screws (21.1%) perforated the pedicle cortex. One screw caused nerve root irritation.

The introduction of CT- based computer-guidance systems into the operation room makes it possible for the first time to insert the screws with the help of real-time three-dimensional images. Several clinical studies, with postoperative CT or MRI examination, showing low pedicle perforation rates, have been published on computer-assisted pedicle screw insertion. Kalfas et al. [5] inserted 150 screws (between the levels L1 and S1), and found, on postoperative CT scans, minimal lateral cortex perforations in 12 screw insertions (8.0%), and a significant lateral perforation without clinical relevance in one screw insertion (0.7%). Amiot et al. [1] reported on 292 screws (between T2 and S1), with 13 screws (4.5%) perforating the pedicle cortex by up to 2 mm. Merloz et al. [8] found three pedicle perforations (5.8%) of less than 2 mm out of 52 screws (T10–L5) in fracture and spondylolisthesis patients, and four perforations (14.3%) of up to 2 mm out of 28 screws (T12–L4) in scoliosis patients. Schwarzenbach et al. [12] reported that four (2.7%) out of 150 lumbosacral screws inserted with computer assistance perforated the pedicle cortex, and 13 (8.7%) were rated as questionable because artefacts on the postoperative CT scan made assessment of the screw position difficult. In an earlier prospective study by the authors of this paper, six (4.3%) out of 139 lumbosacral screws inserted with computer assistance perforated the lateral pedicle cortex by up to 4 mm [7]. A direct comparison of the results of the different study groups is difficult, because the evaluation criteria and the postoperative imaging protocols are not uniform. The material of the screw is also important. According to Yoo et al. [14], the identification rate of pedicle perforations on CT images drops significantly if cobalt-chrome alloy screws are used instead of titanium screws. Kalfas et al. [5] presumably used cobalt-chrome alloy screws. The study of Amiot et al. [1] is based on postoperative transaxial MR images. MRI, however, is known to be inferior to CT in producing images of cortical bone structures. The use of titanium screws and postoperative CT imaging with axial views as well as reformation images of the pedicles seems to be the most effective imaging method available for screw position assessment [6], although the method used by us in this study has not been validated with cadaver studies.

To the best of the authors' knowledge, there are no other published randomised controlled studies comparing computer-assisted pedicle screw placement with conventional screw insertion techniques under clinical conditions. The present study shows that the accuracy of pedicle screw insertion can be improved significantly using image-guided computer navigation. The pedicle cortex perforation rate of 4.6% in the computer-assisted group is comparable to the rate of 4.3% in our earlier prospective uncontrolled study, using the same Bernese optoelectronic navigation system and a similar postoperative evaluation protocol [7]. As in the earlier study, there were no perforations exceeding 4 mm in the computer-assisted group, and all perforations bar one were located laterally. An explanation for perforations occurring laterally is the use of a lateral starting point for screw insertion, the Weinstein approach, to avoid damage to the upper-level facet joints [13]. Also, the screw channel was prepared with a 3.8-mm pedicle probe, and thus, if the screw channel runs close to the lateral cortex of the pedicle, the threads of the screw may cut through. This, however, may even improve screw pull-out strength.

The perforation rate of 13.4% using conventional screw insertion techniques is comparable to figures reported in the literature [2–4,6]. The perforation rate in group 1 would be higher (17.3%) if the 11 screws repositioned during surgery were added. The qualitative difference in the location of perforations is important; 40.0% of the patients in the conventional group had at least one screw perforating the medial or the inferior cortex of the pedicle in the "danger zone", as compared with only 2.4% of the patients in the computer-assisted group. Also, four screws in the conventional group perforated the pedicle from 4 to 6 mm, three medially (L1, L2, S1) and one laterally (L4), but, fortunately, they did not cause nerve root damage. Thus, the superior accuracy of computer-assisted pedicle screw placement is neither reflected in the rate of neurological complications nor in the early postoperative clinical outcome. The only incident directly related to pedicle screw insertion occurred in the conventional group in a 67-year-old female patient with lumbar spinal stenosis. The instrumentation, initially planned from L3 to S1, had to be extended to L2 because of loosening of a repositioned L3 screw.

As a worst case scenario, we also calculated the results if the dropouts were included in the computer-assisted group. In this case, the pedicle perforation rate would be 7.1% (19/268, P = 0.02 vs the conventional group), and the rate of medial or inferior perforations would be 1.5% (5/268, P = 0.00003 vs the conventional group).

Computer navigation is somewhat time consuming. The mean preoperative planning time of 45 min included three steps:

1. The analysis of CT image data for better understanding the pathologic anatomy of the patient
2. Definition and storage of four to six anatomic landmarks from each vertebra to be instrumented for the intraoperative paired-point matching procedure, and

3. Planning the optimal screw trajectories for use in the intraoperative guidance module

Step 1 is not a prerequisite for the use of the system. It should have been measured separately and not included in the actual planning time for computer-assisted screw insertion. However, we found this step especially rewarding, as it enabled us to use the whole preoperative CT data set to study the special features of the anatomy of the patients. Also, some modifications in the operation plan were made due to the new information gained from preoperative planning. Step 2 is the only obligatory one. A surgeon familiar with the system needs 4–6 min per vertebra to perform it. Step 3 is necessary if the intraoperative guidance mode of the system is used. Although we planned all screw trajectories, most of the screws were inserted using the real-time navigation module. Intraoperatively, the time for the whole screw insertion procedure was significantly longer in the computer-assisted group. However, the additional time of 12 min per operation is not much when compared with the mean operating time of 2.5 h, and certainly not too high a price to be paid for the improved accuracy.

We did not have any complications with the computer software during the study. However, technical problems occurred and prevented the use of the computer system in eight patients. In one case the reason was an incomplete preoperative CT image data set due to a fault during data transmission. This has occurred only once since we started with computer surgery over 4 years ago. Intraoperatively, a conversion had to be made in five cases (10%), all because of a problem with a pedicle probe. It was due to an intermittent failure of a light-emitting diode and the coincidence that a second set of instruments was not available. Two operations had to be converted because of computer hardware errors. The mainboard and the hard disc of the computer system were damaged due to overheating in the storage room, not related to the actual use of the computer in the present study.

In our earlier study, matching problems were the main reason that prevented the use of the computer system [7]. Since the introduction of the surface matching technique we have not had such problems.

We had no clinical complications related to the use of computer assistance in this study, and to our knowledge there is no mention of them in the literature. In our opinion, operating with virtual reality images requires an experienced spinal surgeon and thorough knowledge of the computer system to be able to detect a possible system malfunction and to correct it or to proceed with conventional surgical techniques. The successful use of the system requires good training, an exact matching procedure, critical verification of matching accuracy, and an understanding that the system works with rigid bodies, and that it is therefore important to perform frequent matching accuracy checks and to avoid movements of the dynamic reference base.

Did the patients benefit from the navigation system? No primary practical benefit could be demonstrated in this study, despite the significantly lower malplacement rates and the qualitative difference in the perforations. We assume, however, that a higher perforation rate indicates a higher potential for nerve damage, and thus the patients operated with conventional methods were exposed to a higher risk. Whether some of the malpositioned screws will affect the long-term stability of the instrumentation, remains to be seen.

The importance of the present study has to be seen in the broader perspective of the development of computer navigation. Open lumbar pedicle screw insertion has been the first clinical spinal orthopedic application. Our results form a sound base for future innovations, e.g., minimally invasive and percutaneous procedures.

Conclusion

A higher accuracy and reliability of pedicle screw insertion with computer-assisted navigation than with conventional methods was demonstrated under clinical conditions in a randomised controlled trial.

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